NOV 2 9 2002

510K SUMMARY

K023812

Submitted By: ERBE USA, Inc.
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Contact Person: John Tartal

Date Prepared: 11/14/02

Common Name: Patient Plate/Pad, Dispersive Electrode, or Return Electrode

Trade/Proprietary Name: NESSY Ω^{TM} (OMEGA) Disposable Split Return Ele

Classification Name: Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)

Product Code: 79GEI

Legally Marketed Device: ERBE Disposable Patient Return Electrodes, 510(k) Number: K972269

Device Description:

There are two models of the NESSY Ω^{TM} (Omega) Disposable Split Return Electrode. One with a connecting cable (P/N: 20193-084) and the other (P/N: 20193-085) without the cable {Note: A reusable patient return electrode cable submitted in a previous ERBE 510(k) [K960569] is used with this plate/pad}. The cable of the P/N: 20193-084 is made of Polyvinylcholoride (PVC), Copper Wiring, and Polyethylene (PE) Foam. It is flexible, 4 m (13.2 ft.) long, and has a standard connection for fitting into an ESU. The pad portion of each is made of Siliconized Polyethylene Terephthalate (PET), Scantape coated with Acrylic Adhesive, Aluminum, and Hydrogel. There is a protective film cover to keep the pad from drying out prior to being used. The Return Electrode has a peel off tab that makes handling it easier. The plate also is flexible and molds well to the skin. The relatively round external shape and geometrical internal omega design (i.e., the equipotential ring) of the pad more uniformly distributes the High Frequency (HF) current. This was demonstrated through thermographic testing. The design also eliminates the need for orientating the pad to the operative site (i.e., there is no long side of the pad). The hydrogel layer overlaps all the aluminum edges, which reduces warming of the pad during use. The Patient Plate is suitable for use on children and adults. The Electrodes are each packaged in an aluminum foil pouch with a 2-year expiration date. Also, they are provided non-sterile and are disposable.

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Prior to electorsurgery, the NESSY Ω™ (Omega) Disposable Split Return Electrode is placed on the patients skin. AORN (Association of Operating Room Nurses) guidelines are to be followed for site selection, preparation of the site, etc.. The Patient Plate is then attached via a connecting cable to an Electrosurgical Unit (ESU) or Generator. When the ESU is activated, the pad safely returns (disperses) the HF current. If the Generator has a safety monitoring system, the ESU measures the current going into and exiting the pad. In this manner, the Generator monitors the HF current and alerts the clinician to any differences.

Intended Use:

NESSY Ω™ (Omega) Disposable Split Return Electrodes are intended for dispersing and monitoring HF current in electrosurgical interventions.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Similarities
The modified Split Return Electrodes have the same intended use, performance expectations (i.e., safely dispersing/returning delivered HF current and, with the previous split return models, monitoring the current), packaging, and associated labeling as the predicate. As with the predicate, the Patient Plate/Pad comes with or without a connecting cable. Also like the predicate, they are provided non-sterile with the same expiration dating and are disposable.

Finally, the contract manufacturer for the Return Electrodes is the same (Leonhard Lang GmbH).

Differences
The material changes in the modified Split Return Electrode basically involve the pad's carrier being made of Scantape with Acrylic Adhesive (Note: The fabric in band aids.) which molds better to the body and an improved Hydrogel (NH-02). The materials have been found acceptable through biocompatibility testing. Tests were selected based upon EN ISO 10993-1, "Biological Evaluation of Medical Devices".

For the modified Electrode with a cable, the cord is 1 m (3.3 ft.) longer than the predicate devices that have a cable [i.e., the predicate device cable is 3 m (10 ft.) long in comparison to 4 m (13 ft.) for the modified product that has a cable]. The extra length provides the clinician with a little more latitude in regards to the position of the patient and equipment location.

The pad of the modified Split Return Electrodes, are designed with an equipotential ring. The round/omega design of the conductive films distributes HF current more evenly. As a result, only one size pad (i.e., contact surface) is needed. Also, due to the symmetrical design of the plate, there is no long side. Therefore, no orientation of the pad to the operative site is needed.

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All the changes have been verified or validated in design control. Applicable sections of AAMI/ANSI HF-18, "Electrosurgical Devices"; EN/IEC 60601-1, "Medical Electrical Equipment, General Requirements for Safety; and EN/IEC 60601-2-2, "Medical Electrical Equipment, Particular Requirements for the Safety of High Frequency Surgical Equipment" standards were applied and met for the modified Split Return Electrodes.

Conclusion:

The modified Split Return Electrodes have the same intended use and principles of operation as the Split Return Electrodes in the previously cleared predicate device. Technologically the modified electrode's round/omega design of the pad's conductive films disperses HF current more evenly. As a result, the NESSY Ω™ (Omega) Disposable Split Return Electrodes are as safe and effective then the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Erbe USA, Inc.
John Tartal
QA/RA Manager
2225 Northwest Parkway
Marietta, Georgia 30067

Re: K023812
Trade/Device Name: Nessy Ω™ (Omega) Disposable Split Return Electrodes
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 14, 2002
Received: November 15, 2002

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K023812

DEVICE NAME: NESSY Ω™ (Omega) Disposable Split Return Electrodes

INDICATIONS FOR USE:

NESSY Ω™ (Omega) disposable split return electrodes are intended for dispersing and monitoring HF current in electrosurgical interventions.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023812

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER P
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-
(Optional Forma